



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/373,272	08/12/1999	SANDRA AUSTIN-PHILLIPS	09820.114	2404

7590 11/23/2001

INTELLECTUAL PROPERTY DEPARTMENT
DEWITT ROSS & STEVENS SC
FIRSTAR FINANCIAL CENTRE
8000 EXCELSIOR DRIVE SUITE 401
MADISON, WI 537171914

EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 11/23/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/373,272	AUSTIN-PHILLIPS ET AL.
	Examiner	Art Unit
	Janet L. Epps	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 September 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 16-22 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 16-22 and 26 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received. *WILLIAM N. PHILLIPS*
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or *PATENT ANALYST*

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other:

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Claims 16-20, 21-22, and 26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Van Ooyen et al. in view of Virki et al. (WO 9320714), Henrissat et al., and Willmitzer et al. (PTO-1449), and further in view of Shiyaron et al. (GenBank Accesion No. E00389) and Thomas et al. for the reasons of record set forth in the Official Action mailed 6-05-2001.

It is also noted that the instant prior art rejection is maintained to the extent that the instant claims read on transgenic plants expressing *T. reesei* CBH I (SEQ ID NO: 9), and *A. cellulolyticus* endoglucanase E1 (SEQ ID NO: 8).

Applicant's arguments filed 9-07-2001 have been fully considered but they are not persuasive. Applicants traverse on the grounds that combination of the Van Ooyen et al., Virki et al.; Henrissat et al., and Willmitzer et al. references do not necessarily enable the transgenic expression of the particular polysaccharide-degrading enzymes explicitly recited in the claims. Furthermore, Applicants traverse on the grounds that the Office has inappropriately taken the position that "merely because Van Ooyen mentions the transgenic expression of 'any enzymes or combination of enzymes which are capable of degrading plant polysaccharides' the reference necessarily enables the expression of all such polysaccharide-degrading enzymes in a plant host....this is an overly broad interpretation of the Van Ooyen reference." Additionally, Applicants have provided multiple citations of case law that relate to Applicant's position

regarding the inappropriateness of the Office's making of a *prima facie* case based upon the argument of structural or functional equivalence.

First in regards to the question of the prior art reference providing sufficient guidance and/or instruction to enable one of skill in the art to practice the claimed invention, it is noted that the teachings of the Van Ooyen et al. reference uses the same plant binary vector transformation system for expressing genes in plant tissue as described in Applicant's specification, namely the *Agrobacterium tumafaciens* transformation system (Van Ooyen et al., col. 5, line 56; col. 7, lines 27-43). Applicant's own specification recites that "[T]ransformation of the plants can be accomplished by any means known to the art, including *Agrobacterium*-mediated transformation, particle bombardment, electroporation, and virus-mediated transformation....*Agrobacterium tumafaciens*...is the preferred strain for transformation."

Applicants have not provided any clear evidence that it would require one of skill in the art undue experimentation to use the plant transformation system disclosed in Van Ooyen et al. to express the plant polysaccharide degrading enzymes according to SEQ ID NO: 8 and 9 in a either a tobacco plant or an alfalfa plant. There is no evidence that there is a sufficient level of unpredictability in the art with regards to plant transformation that would warrant an undue amount of experimentation to practice the invention disclosed in the combined references.

Applicants have not weighed the appropriate factors that would lead one to conclude that the combined references are not enabling with regards to the claimed invention (see *In re Wands*).

Applicants argue that "unlike the transgenic enzymes actually described in Van Ooyen, the transgenic plants recited in Claims 19 and 20 express cellulose-degrading enzymes that might very well have been highly destructive of the plant itself. Until the transformation was

successfully completed by the present inventors, it could not have been predicted with any degree of certainty whether the transformation could be accomplished or not (page 12 of Response 9-07-2001).” However, contrary to applicant’s assertions, the Van Ooyen et al. reference provide a clear suggestion and guidance to design transgenic plants expressing cellulases (col. 4, lines 31-36) according to SEQ ID NO: 8 (EC 3.2.1.4) and 9 (EC 3.2.1.91) of the instant application, provides the same binary vector plant transformation system as suggested by Applicants. Additionally, this reference provides examples wherein they have successfully isolated transgenic plants expressing microbial polysaccharide degrading enzymes in tobacco and potatoes, and an example wherein they have successfully expressed two microbial polysaccharide degrading enzymes simultaneously in a transgenic plant. Based upon the number of working examples provided by Van Ooyen et al., the similarity in the methods used in the design of transgenic plants as compared to Applicant’s teachings in the specification as filed, the apparent predictability with regards to genetic engineering of plants (see Van Ooyen et al. col. 1, lines 40-55, which states “[C]hanging plant characteristics through genetic engineering is a precise and predictable method...”), the clear suggestion to design transgenic plants expressing cellulases and endoglucanases as taught by Van Ooyen et al., and the availability of Applicant’s sequences according to SEQ ID NO: 8 and 9 in the prior art as taught by Thomas et al. and Shiyaron et al., one of skill in the art would have had significant expectation of success, and motivation to synthesized Applicant’s claimed transgenic plants.

Applicants object to the Office’s establishment of a *prima facie* case of obviousness based upon “functional equivalence.” According to Applicant’s, modifying the teachings of Van Ooyen et al. with the sequences of Shiyaron et al. and Thomas et al. is inappropriate since they

are “structurally distinct” from the polysaccharide-degrading enzymes described in Van Ooyen et al. Contrary to Applicant’s assertions, Van Ooyen et al. clearly provides motivation for transgenic plants expressing the sequences of Thomas et al. and Shiyaron et al. for the reasons set forth above, and to the extent that the microbial enzymes recited in these references fall within the class of enzymes that are disclosed as “capable of use in conjunction with” the Van Ooyen et al. invention (see col. 4, lines 23-37). Therefore, these sequences are not only functionally equivalent to those enzymes useful in the Van Ooyen et al. reference, they are also structurally equivalent as well. Applicant’s arguments and citation of multiple case law references are not considered applicable in the instant case, since the facts set forth in the cases mentioned by Applicants are not applicable in the instant case wherein the prior art both discloses the genus of polysaccharide degrading enzymes but also discloses the specific species of enzymes recited by Applicants.

Moreover, in response to Applicant’s citation of *Amgen, Inc. v. Chugai Pharmaceutical Co.*, to support their argument that “*a prima facie* case of obviousness cannot be established in the reverse direction, i.e., starting from function and extending to structure.” In the instant case, as stated above the sequences of Thomas et al. and Shiyaron et al. are structurally and functionally encompassed by the enzyme classes according to EC 3.2.1.91 and EC 3.2.1.4, wherein enzymes according to the mentioned classes are disclosed as capable of use in conjunction with the invention of Van Ooyen et al.

Applicants argue that the Office’s “stated reason for relying on Henrissat is that it teaches the (presumably) desirable synergism of cellulose mixtures. However, this motivation is directly contradicted by the teaching of Vikri et al.” Applicant’s point is uncertain since the invention of

Vikri et al. is clearly drawn to improving the nutritional value of crops by providing highly purified compositions comprising a combination of cellulolytic enzymes. See for example, the Summary of the Invention of the Vikri et al. reference which states “[B]y the fractionation of said commercial enzymes in accordance with this invention novel enzyme products have been obtained, each containing several individual enzymes and having its own characteristic features...”

Moreover, Applicants argue that the Willmitzer is “completely silent regarding the expression of *T. fusca* cellulase E2, *T. fusca* cellulase E3, *T. reesei* CBH I, and *A. cellulolyticus* endoglucanase E1 in an alfalfa or tobacco host.” However, contrary to Applicant’s assertions, the Willmitzer et al. reference was not presented by the examiner as disclosing such limitations. The Willmitzer et al. was included in the combination of references to provide direct motivation for expressing industrial enzymes in plants, particularly for the transgenic expression of microbial and industrial enzymes that improve the nutritive value of feed (page 7, lines 12-16), such as cellulases (page 6, lines 19-20), and further provides teachings for the production of transgenic tobacco plants expressing said enzymes (page 11, lines 9-22).

Moreover, Applicants argue that the combined references do not provide motivation for expressing plant polysaccharide degrading enzymes specifically for ensilage purposes. However, as stated above, the Willmitzer et al. reference provide teachings for the use of transgenic plants expressing enzymes, including cellulases, for the improvement of the nutritive value of feed, i.e. ensilage. Although, the term “ensilement” is not specifically mentioned in these references one of skill in the art would recognize that the teachings of Willmitzer et al. would necessarily encompass a method of ensilment.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 16-18, and 21-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 13-17 of U.S. Patent No. 5,981,835. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the issued patent encompasses certain claimed species of genetically recombinant plants recited in the claims of the instant invention. The claims of the issued patent recites a genetically recombinant plant transformed with an exogenous gene sequence selected from the group consisting of SEQ ID NO: 1 (which corresponds to *T. fusca* cellulase E2) and SEQ ID NO:3 (which corresponds to *T. fusca* cellulase E3), wherein said plant is either tobacco or alfalfa, and methods for producing cellulose degrading enzymes comprising cultivating said genetically recombinant plants. Similarly, the claims of the instant invention are

drawn to a genetically recombinant tobacco or alfalfa plant that is transformed to contain and express a gene sequence which encodes a cellulase-degrading enzyme selected from the group consisting of *T. fusca* cellulase E2 , *T. fusca* cellulase E3, *T. reesei* CBH I, and *A. cellulolyticus* endoglucanase E1, and methods for producing cellulose degrading enzymes comprising cultivating said genetically recombinant plants. Therefore, since Applicants have already been granted a patent drawn to the same species of genetically recombinant plants, namely genetically recombinant tobacco and alfalfa plants expressing *T. fusca* cellulase E2 , and *T. fusca* cellulase E3, and the same method of using said plants as recited in the instant application, the grant of an additional patent reciting the claims of the instant invention would unlawfully extend Applicant's right to exclude others from making and/or using the instant invention.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet Lee Epps
Patent Examiner
November 12, 2001

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600